

### REMARKS/ARGUMENTS

This responds to the final office action issued on March 17, 2005.

In the specification, the paragraph under RELATED APPLICATION has been amended to correct the priority claim.

Claims 53-58 and 61-63 are currently pending. Claim 53 is independent. Claims 54-58 and 61-63 are dependent.

In the office action, the only grounds for rejection stated with respect to independent claim 53 is an anticipation rejection over United States Patent No. 5,366,490 (Edwards et al.). As the Examiner will note, independent claim 53 includes the recitation of “a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening.” In the office action it is contended that a “tubular member (138, 72 or 60) having a lumen and a distal end opening” disclosed by Edwards et al. satisfies the requirement of “a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening” recited in independent claim 53. Applicant respectfully disagrees with this reasoning.

In Edwards et al., the items designated by reference numerals 138, 72 and 60 are clearly not tissue penetrating elements that have lumens and tissue penetrating distal tips. In fact, reference numeral 138 does not refer to a physical component of the device, but rather refers to a “dotted line path” over which a “stylet can be advanced.” (col. 8, lines 43-44) The “stylet” is indicated by reference numeral 132. Edwards et al. disclose no lumen within the stylet 132. Thus, the stylet is not “tubular.” Therefore, neither the stylet 132 nor its dotted line path 138 can possibly satisfy applicant’s claimed limitation of “a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening.”

Reference numeral 72 refers to an insulating sleeve or coating that encloses a “wire mesh or tube 68.” Edwards et al. discloses no tissue penetrating distal tip on either the “insulating sleeve or coating 72” or the “wire mesh or tube 68” that it surrounds. In fact, the tip of the solid stylet 132 protrudes out of the distal end of the “wire mesh or tube 68” and it is the solid stylet that is “advanced into tissue.” (col. 8, lines 9-14) Thus, neither the “insulating sleeve or coating 72” nor the “wire mesh or tube 68” that it surrounds can possibly satisfy the claimed limitation of “a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening.”

Reference numeral 60 refers to sleeve which encloses a tube 58. Neither the sleeve 60 nor the tube 58 are described as having any tissue penetrating distal tip as required by applicant’s claim 54. In fact, Edwards et al. explains at column 7, lines 48-51 that, in such embodiment, a “a stylet 54” that comprises “a solid core needle 56” is coaxially positioned within the tube. It is the tip of that “solid” needle 56 that penetrates into tissue. Thus, neither the sleeve 60 nor the tube 58 that it surrounds can possibly satisfy the claimed limitation of “a tissue penetrating element having a lumen, a tissue penetrating distal tip and a distal end opening.”

Moreover, independent claim 53 specifically states that it is directed to a system that is useable to “guide the advancement of a guidewire from a location within the lumen of a blood vessel to a location within or outside of the wall of that blood vessel.” In fact, the system recited in claim 53 specifically includes “a guidewire that is advanceable through the lumen of the tissue penetrating element while the tissue penetrating element is in the second position.” In contrast, the Edwards et al. device is used to deliver ablative energy to the prostate gland, not to guide the placement of a guidewire. In the office action, the items identified in Edwards et al. by reference numerals 56 and 66 are stated to be guidewires. This is not correct. As explained above reference numeral 56 refers to a “solid core needle.” (col.7, line 48) Also, reference numeral 66 refers alternately to a “conductive needle wire” (col.8, line 9) and a “needle antenna.” (col. 8, line 17). Thus, neither of these items is a “guidewire” as recited in claim 53.

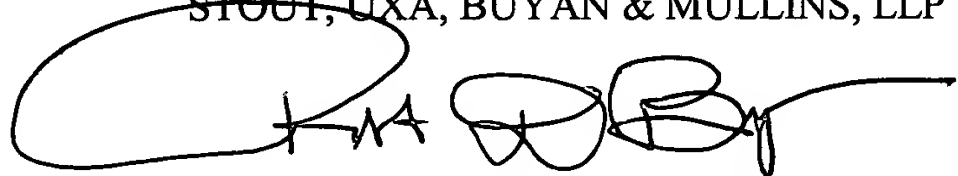
For the above stated reasons and possibly others not specifically articulated here, Applicant respectfully requests reconsideration and withdrawal of the rejection of independent claim 53 and all dependent claims 54-58 and 61-63. The Examiner is invited to telephone Applicant's undersigned counsel to discuss any measures that may be taken to advance prosecution and facilitate issuance of a notice of allowance in relation to this application.

A substitute specification is enclosed herewith as requested. This substitute specification contains no new matter.

No fee is seen to be due in connection with this filing. However, in the event that any fee is properly deemed to be due, the Examiner is authorized to deduct such fee from Deposit Account No. 50-0878.

Date: May 17, 2005

Respectfully submitted,  
STOUT, LXA, BUYAN & MULLINS, LLP

A handwritten signature in black ink, appearing to read "R. Buyan", with a long horizontal flourish extending to the right.

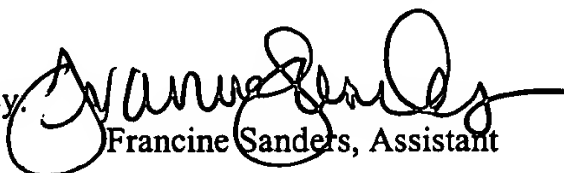
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Case No.: TRANS-015A

Pat. Appln.

CATHETERS AND RELATED DEVS

5 BETWEEN BLOOD VESSELS OR OTHER ANATOMICAL STRUCTURES

Related Application

10 This patent application is a continuation-in-part of  
co-pending United States Patent Applications Serial  
No. 08/730,327 filed October 11, 1996 and 08/730,496 filed  
October 11, 1996, the entire disclosures of which are  
expressly incorporated herein by reference.

Field of the Invention

15 The present invention relates generally to medical  
devices and methods, and more particularly to catheters,  
catheter positioning/aiming systems, and related methods  
for forming interstitial passageways (e.g., interstitial  
tunnels) between two or more adjacently situated blood  
20 vessels or other anatomical structures.

Background of the Invention

Applicant has invented novel methods for bypassing  
obstructions in arteries and for performing other  
transvascular medical procedures, wherein a catheter device  
25 is inserted transluminally into the blood vessel or other  
luminal anatomical structure and a tissue-penetrating  
element (e.g., a puncturing member or a flow of energy) is  
passed out of the catheter, through the wall of the blood  
vessel or other anatomical structure in which the catheter  
30 is positioned, and into a second blood vessel or other  
target anatomical structure. In this manner one or more  
interstitial passageways is/are formed from the blood  
vessel or other luminal structure in which the catheter is  
positioned, to a second blood vessel or other target  
35 tissue. These transvascular procedures, and certain

passageway forming catheters which are useable to perform these procedures, have previously been described in United States Patent Applications Serial No. 08/730,327 entitled METHODS AND APPARATUS FOR BYPASSING ARTERIAL OBSTRUCTIONS  
5 AND/OR PERFORMING OTHER TRANSVASCULAR PROCEDURES, filed on October 11, 1996 and 08/730,496 entitled, A DEVICE, SYSTEM AND METHOD FOR INTERSTITIAL TRANSVASCULAR INTERVENTION, filed October 11, 1996.

In performing the above-summarized transvascular  
10 procedures, it is important that the passageway-forming catheter be properly positioned and oriented within the body in the order to ensure that the tissue-penetrating element will form the desired interstitial passageway, at the desired location. If the catheter is improperly  
15 positioned or improperly oriented, the resultant passageway(s) may fail to perform their intended function (e.g., to channel blood from one location to another) or the tissue penetrating element of the catheter may perforate or traumatize tissue(s) other than those intended  
20 to be canalized.

In many of the passageway-forming catheters devised by applicant, it is necessary to precisely control the rotational orientation of the catheter in order to accomplish the desired aiming of the tissue-penetrating  
25 element. However, when the passageway-forming catheter is formed of relatively small diameter, thin-walled polymeric material capable of navigating small, tortuous blood vessels, the catheter shaft may lack sufficient structural integrity to efficiently transfer torque from the proximal  
30 end of the catheter to the distal end thereof. Such diminished torque transfer of the catheter shaft can prevent or interfere with the precise rotational orientation and positioning of the distal portion of the catheter prior to formation of the extravascular  
35 passageway.

Additionally, to facilitate the use of any on-board imaging system (e.g., an intravascular ultrasound system inserted or built into the passageway-forming catheter) or any separate intracorporeal or extracorporeal imaging services intended to assist in the precise aiming of the tissue-penetrating element, it is desirable for the tissue-penetrating catheter to be provided with appropriate markers or other indicia to enable the operator to utilize to discern the present rotational orientation and position of the catheter and the projected path of the tissue-penetrating element.

Thus, there remains a need in the art for further development and modification of applicant's previously described passageway-forming catheter devices so as to provide for i) improved torque transfer to the distal portion of the catheter and ii) precise rotational orientation and aiming of the catheter prior to deployment of the tissue penetrating element.

#### Summary of the Invention

The inventions described in this patent application include i) a torqueable introducer sheath which is useable in conjunction with a transvascular passageway forming catheter to effect precise rotational control of the catheter; ii) an anchorable guide catheter which is useable in conjunction with an intravascular imaging catheter and a transvascular passageway-forming catheter to effect precise positioning and aiming of the passageway-forming catheter; iii) a passageway forming catheter having a torqueable proximal portion to facilitate precise rotational positioning of the distal portion of the catheter; iv) a deflectable-tipped passageway forming catheter; v) various markers and other apparatus useable in conjunction with any of the passageway-forming catheters to facilitate precise positioning and aiming of the catheter, and vi) an apparatus which may be formed within a catheter

to prevent a member, apparatus of flow of material from being inadvertently advanced through a lumen of the catheter.

Additional details and objects of each of the above-summarized inventions will become apparent to those skilled in the art upon reading and understanding of the following detailed descriptions of preferred embodiments and the accompanying drawings.

Brief Description of the Drawings

Figure 1 is a perspective view of a torqueable sheath through which a passageway-forming catheter of the present invention may be inserted, and which may be used to facilitate subsequent rotational positioning of the distal portion of the passageway-forming catheter.

Figure 1a is a cut-away perspective view of the distal end of the torqueable sheath of Figure 1, and shown in phantom lines the preferred operative positioning of a passageway-forming catheter within such torqueable sheath.

Figure 1b is a partial cut-away perspective view of portion 1b of Figure 1, showing the braided wire layer formed within the proximal portion of the torqueable sheath.

Figure 1c is a cross-sectional view through line 1c-1c of Figure 1.

Figure 1d is a cross-sectional view through line 1d-1d of Figure 1.

Figure 1e is a cross-sectional view through line 1e-1e of Figure 1.

Figure 1f is a perspective view of a typical passageway-forming catheter of Applicant's invention, as previously described in United States Patent Application Serial No. 08/730,327, entitled METHODS AND APPARATUS FOR BYPASSING ARTERIAL OBSTRUCTIONS AND/OR PERFORMING OTHER TRANSVASCULAR PROCEDURES filed on October 11, 1996.

Figure 1g is a cross-sectional view through line 1g-1g

of Figure 1f, and additional showing in phantom lines the preferred operative positioning of a torqueable sheath of the present invention relative to that portion of the passageway-forming catheter.

5        Figure 2 is a perspective view of a guide catheter of the present invention having an anchoring balloon formed on the distal end thereof.

10        Figure 2a is a partial longitudinal sectional view through line 2a-2a of the guide catheter of Figure 2, showing an intravascular ultrasound device operatively inserted into the guide catheter.

Figure 2b is a cross-sectional view through line 2b-2b of the guide catheter Figure 2 having an intravascular ultrasound catheter operatively inserted therethrough.

15        Figure 2c is a cross-sectional view through line 2c-2c of Figure 2a.

20        Figure 2a' is a partial longitudinal sectional view through line 2a-2a of the guide catheter of Figure 2, showing a passageway-forming catheter of the present invention operatively inserted into the guide catheter.

Figure 2b' is a cross sectional view through line 2b-2b of the guide catheter of Figure 2 having a passageway-forming catheter of the present invention operatively inserted therethrough.

25        Figure 2c' is a cross-sectional view through line 2c'-2c' of Figure 2a'.

30        Figure 3 is a perspective view of the passageway forming catheter of the present invention which is useable in conjunction with the guide catheter shown in Figures 2-2c'.

Figure 3a is a perspective view of portion 3a of Figure 3.

Figure 3b is a longitudinal sectional view through line 3b-3b of Figure 3a.

35        Figure 3c is a cross-sectional view through line 3c-3c



of Figure 3.

Figure 3d is a cross-sectional view through line 3d-3d of Figure 3.

Figure 4a is a perspective view of a torqueable  
5 passageway-forming catheter device of the present invention.

Figure 4b is a cross-sectional view through line 4b-4b of Figure 4a.

Figure 4c is a cross-sectional view through line 4c-4c  
10 of Figure 4a.

Figure 4d is a perspective view of the distal portion of a passageway-forming catheter of the present invention incorporating a first marker thereon.

Figure 4e is a perspective view of the distal portion  
15 of a passageway forming catheter of the present invention incorporating a second marker thereon.

Figure 4f is a perspective view of the distal portion of a passageway forming catheter of the present invention incorporating a third marker thereon.

Figure 4g is a longitudinal sectional view of the  
20 distal portion of a passageway-forming catheter having a fourth marker of the present invention formed thereon.

Figure 4h is a longitudinal section view of the distal  
25 portion of a passageway forming catheter having a fifth marker formed thereon.

Figure 4h' is a longitudinal sectional view of the  
passageway forming catheter of Figure 4h wherein the marker  
has been advanced to its operative position by insertion of  
an IVUS catheter through one lumen of the passageway-  
30 forming catheter.

Figure 4i is a perspective view of the distal portion of a passageway forming catheter having a sixth marker formed thereon.

Figure 4i' is a perspective view of the distal portion  
35 of a passageway forming catheter having a variation of the

sixth marker of Figure 4i formed thereon.

Figure 4j is an elevational view of the distal portion of a passageway forming catheter having a seventh marker formed thereon.

5        Figure 4j' is an elevational view of the distal portion of the passageway catheter of Figure 4j wherein the seventh marker has been advanced to an operative position by insertion of an IVUS catheter through one lumen of the passageway forming catheter.

10        Figure 4k is a longitudinal sectional view of the distal portion of a passageway forming catheter wherein i) a reduced-diameter guidewire lumen has been formed to permit a guidewire to be temporarily advanced into such guidewire lumen to act as a marker to facilitate precise  
15        rotational positioning of the catheter, and ii) an ultrasound chip has been mounted on the catheter adjacent the outlet opening for the tissue penetrating element so as to cause ultrasonic vibration and enhanced imageability of the tissue penetrating element when it is deployed out of  
20        the opening.

Figure 4l is an exploded perspective view of a modified passageway-forming catheter, and a modified phased-array IVUS catheter useable in conjunction therewith to effect precise rotational positioning of the passageway-  
25        forming catheter.

Figure 4l' is a schematic diagram of one type of system which may be utilized to electronically mark or differentiate the image received from a single crystal on the phased array imaging catheter of Figure 4l.

30        Figure 4m is a perspective view of the distal portion of a passageway forming catheter having an eighth marker formed thereon.

Figure 4m' is an elevational view of the distal portion of a passageway forming catheter having a variant  
35        of the eighth marker of Figure 4m formed thereon.

Figure 5 is a longitudinal sectional view of an adjacent artery and vein, showing an energy-emitting/receiving guidance and positioning system of the present invention which is useable to effect precise  
5 positioning and rotational orientation of the passageway-forming catheter.

Figure 5a is a partial longitudinal sectional view of a passageway-forming catheter of the present invention having an alternative aiming/positioning system formed  
10 thereon, such system comprising an active (emitting) component and a passage (receiving) component.

Figure 5b is a partial longitudinal sectional view of another passageway-forming catheter of the present invention which incorporates another aiming/positioning  
15 system thereon, such system comprising an active (e.g., emitting) component mounted on the body of the catheter and an imaging catheter component (e.g., an IVUS catheter) advanceable through an imaging catheter lumen of the passageway-forming catheter to image the target tissue  
20 after the target tissue has been affected by energy received from the active (emitting) component.

Figure 5c is a partial longitudinal sectional view of another passageway forming catheter of the present invention having an alternative aiming/positioning system  
25 wherein the tissue penetrating element of the catheter is an elongate member having a sensor mounted thereon for sensing the location of the target tissue.

Figure 5d is a partial longitudinal sectional view of another passageway forming catheter of the present  
30 invention (having an alternative aiming/positioning system wherein an active (e.g., emitting) component is mounted in specific relation to the outlet port for the tissue-penetrating element, and is adapted to emit a signal to an imaging component (e.g., IVUS catheter) to accentuate the  
35 location of the outlet port and facilitate aiming of the

catheter by use of the imaging device.

Figure 5e is a schematic diagram of one type of system which may be utilized to peak a signal received from the passive (e.g., receiving) component of an aiming/positioning system of Figures 5-5c hereabove.

Figure 6 is a schematic showing of the manner in which an extracorporeal imaging apparatus is useable in conjunction with a marking scheme formed on a passageway-forming catheter of the present invention, to effect precise positioning and rotational orientation of the passageway-forming catheter.

Figure 6a is a showing of a first marking scheme useable with the extracorporeal imaging system of Figure 6.

Figure 6b is a showing of a second marking scheme useable with the extracorporeal imaging system of Figure 6.

Figure 6c is a showing of a third marking scheme useable with the extracorporeal imaging system of Figure 6.

Figure 7 is a perspective view of a deflectable-tipped passageway forming catheter system of the present invention which comprises a) a deflectable tipped catheter; b) an imaging component which is advanceable through the deflectable-tipped catheter and c) a tissue-penetrating component which is passable through the deflectable-tipped catheter.

Figure 7a is a longitudinal sectional view of the handpiece portion of the deflectable tipped portion of Figure 7.

Figure 7b is a longitudinal sectional view of the distal portion of the deflectable-tipped catheter of Figure 7.

Figure 8 is a longitudinal sectional view of another passageway-forming catheter which incorporates apparatus for preventing deployment of the tissue-penetrating element.

Figure 8' is a longitudinal sectional view of another

passageway-forming catheter which incorporates apparatus for preventing deployment of the tissue-penetrating element and for stabilizing the catheter within a luminal anatomical structure, wherein such apparatus is in an initial configuration whereby the lumen is blocked and the catheter is unstabilized.

Figure 8'' is a longitudinal sectional view of another passageway-forming catheter which incorporates apparatus for preventing deployment of the tissue-penetrating element and for stabilizing the catheter within a luminal anatomical structure, wherein such apparatus is in an operative configuration wherein the lumen is open and the catheter is stabilized.

#### Detailed Descriptions Preferred Embodiments

The following detailed description and the accompanying drawings are provided for the purpose of describing and illustrating presently preferred embodiments of the invention only, and are not intended to limit the scope of the invention in any way.

It is to be appreciated that the individual elements and components of each of the embodiments described herebelow may be individually or collectively incorporated into each of the other embodiments capable of receiving or incorporating such element(s) or component(s), and no effort has been made to exhaustively describe all possible permutations and combinations of the inventive elements and components described herein.

##### i. Torqueable Introducer Sheath

Referring specifically to Figures 1-1g, the present invention includes a torqueable introducer sheath comprising an elongate pliable tubular sheath body 12 having a proximal end PE and a distal end DE. The tubular sheath body 12 comprises a proximal segment 14, a medial segment 16 and a distal segment 18. A hollow lumen extends longitudinally through the tubular sheath body 12,

such hollow lumen 20 being defined by an inner luminal surface 22. A proximal hand piece or connector assembly 24 may be mounted on the proximal end PE of the sheath body 12 to facilitate manipulation of the proximal end PE of the sheath body 12 and to receive and register against the hand piece 26 of any catheter which is inserted through the torqueable introducer sheath 10.

A tubular catheter engaging member 28 is formed or mounted within the lumen 20 of the distal segment 18 of the tubular sheath body 12. Such tubular catheter engaging member 28 has a lumen 30 which extends longitudinally therethrough. The lumen 30 may be of any non-cylindrical or nonuniform configuration, such as "pair shape" or "egg-shape," whereby the luminal surface or a portion thereof will engage and prevent rotation of the catheter inserted through the sheath. An example of a generally oval shaped lumen is shown in Figure 1a.

A plurality of elongate reinforcement members 32, formed of wire, fibers or other suitable material, are disposed within the proximal and medial segments 14, 16 of the tubular sheath body 12. These reinforcement members 32 may be helically wound about the lumen 20 of the sheath body 12 to form an overlapping braid structure 34. Other structures, such as a coil structure, may also be used. In particular, such overlapping braid structure 34 may comprise two groups of individual elongate members 32 helically wound in opposite phase about the longitudinal axis LA of the tubular introducer sheath body 12, and at cross over points of such groups of elongate members 32, the individual elongate members 32 of one group will be alternately passed over and under the individual elongate members 32 of the other group, so as to provide a braid structure 34 which will impart enhanced structural integrity and torque transfer to the proximal 14 and medial 16 segments of the tubular sheath body 12. In some

embodiments, the distal segment 18 may also be provided with the elongate members 32 and/or braided structure.

In embodiment of this sheath intended for coronary application, the individual elongate members 32 may preferably be formed of stainless steel of 0.001-0.005 inch diameter. Each group of elongate members 32 may consist of eight such stainless steel wire members in substantially parallel side-by-side relation to one another. The first and second groups of elongate members 32 will be helically wound about a tubular inner liner 36, in opposite phase such that the first and second groups of elongate members will repeatedly cross over each other. At locations whereat the groups of elongate members 32 cross over each other, each individual elongate member 32 of each group may be alternately threaded over and under the individual elongate members 32 of the other group, so as to provide an interwoven, braided structure 34 which will impart enhanced torqueability to the tubular sheath body 12. A tubular outer skin 15 is then formed over the wire braid structure 34 such that the wire braid structure 34 is captured or located between the tubular outer skin 15 and the tubular core member 36, as shown.

In at least some applications it may be desirable to impart regionalized differences in rigidity or hardness to the proximal and medial segments 14, 16 of the tubular sheath body 12. In this manner, the outer skin 15 of the proximal portion 14 may be formed of material which is more rigid or greater in hardness than that of the outer skin 15 of the medial portion 16. For example, the outer skin 15 of the proximal portion 14 may be formed of thermoplastic, elastin (e.g., Pebax, polyurethane, silicone, polyester) or thermoset elastomer (e.g., polyurethane or flexibly epoxy) (e.g., Pebax) having a Shore D hardness of 60-72 while the outer skin 15 of the medial portion 16 may be formed of polymeric material (e.g., pebax) having a lesser hardness,

such as a 40-60 Shore D hardness on the shore D scale. The outer skin 15 of the distal portion 18 may preferably have a Shore D hardness in the range of 30-40. The relative lengths and hardness of the inner liner 36 and outer skin 15 may be varied to adjust the overall stiffness of the catheter and the locations of the transition areas between the proximal 14, medial 16 and distal 18 segments of the sheath 10.

In the preferred embodiment, shown in the drawings, the inner liner is formed of polytetrafluoroethylene (PTFE) of consistent hardness from the proximal end PE to the distal end DE of the tubular sheath body 12.

With reference to Figures 1f-1g, one type of passageway-forming catheter 40 which is useable in conjunction with the torqueable sheath 10 comprises an elongate pliable catheter 40 having an irregular cross sectional configuration defining an upper portion 42 through which a tissue-penetrating element 46 may pass and a lower portion 44 through which an imaging catheter (e.g., an IVUS catheter) may pass.

A tissue-penetrating element 46 of the type previously described in United States Patent Application Serial No. 08/730,327 is advanceable out of the distal end DE of the upper catheter portion 42 such that the tissue penetrating element 46 will diverge laterally from the longitudinal axis LA of the catheter device 40. In this manner, the tissue-penetrating element 46 will pass through the wall of a blood vessel wherein the distal portion of the catheter device 40 is positioned so as to create an extravascular passageway extending from the blood vessel to another blood vessel or other extravascular target location.

As shown in Figure 1g, when the catheter 40 is advanced through the torqueable introducer sheath 10, the upper portion 42 of the catheter body will engage the smaller diameter side of the lumen 30 of the catheter



engagement member 28, while the relatively large diameter lower catheter portion 44 will engage the opposite end of such lumen 30, and the passageway-forming catheter 40 will be thereby prevented by the catheter engaging insert 28  
5 from rotatably moving relative to the tubular body 12 of the sheath 10. In this manner, the operator may manually grasp the proximal connector 24 and may apply rotational force to the proximal connector 24, such that the rotational force will be transmitted through the tubular  
10 sheath body 12 so as to cause the distal segment 18 of the tubular sheath body 12 to rotate in a substantially one to one (1:1) relation to the proximal connector 24. In this manner, the torqueable introducer sheath 10 will cause the catheter 40 which has been inserted through the sheath 10  
15 to rotate in conjunction with the sheath 10, irrespective of whether the body of the catheter 40 has sufficient structural integrity to be capable of transmitting torque from its proximal end to its distal end. This construction allows the use of a passageway-forming catheter 40 which is  
20 of relatively small diameter and formed of pliable or subtle material, while the torqueable sheath 10 may be of stronger and less pliable material capable of transmitting torque and acting as guide for insertion of the catheter 40. Additionally, the catheter engaging insert 28 may be  
25 positioned at or near the distal end of the sheath 10 so as to transmit torque to the catheter 40 at a location at or near its distal tip, thereby eliminating torque or rotational stress on the majority of the catheter shaft and eliminating the potential for kinking or buckling of the  
30 small diameter, pliable catheter body. In this manner, the use of the sheath 10 of the present invention in conjunction with the catheter 40 provides for the maintenance of precise rotational control of the distal portion of the catheter 40.

ii. Anchorable Guide Catheter

Referring to Figures 2-2b' there is provided an anchorable guide catheter which is useable in conjunction with i) an imaging catheter such as a commercially available IVUS catheter (e.g., 29 French Ultra-Cross available from Boston Scientific, 27 Orleans Dr., Sunnyvale, California) and ii) a transvascular passageway forming catheter, one example of which is shown in Figures 3a-3d of this application and other examples of which are described in U.S. Patent Applications Serial No. 08/730,327 and 08/730,496.

The anchorable guide catheter 50, comprises a pliable tubular catheter body 52 having a proximal end PE and a distal end DE. First and second lumens 54, 56 extend longitudinally through the catheter body 52. An opening 58 is formed in one side of the catheter body 52, so as to provide an opening into the first lumen 54. A pressure exertive member such as a balloon 59 or other projectable apparatus such as a moveable foot, is mounted on the catheter body 52 at a location laterally opposite the location of the opening 58. An inflation fluid aperture 60 is formed in the sidewall of the catheter body 52 between the balloon 58 and the second lumen 56 such that balloon inflation fluid may pass into and out of the balloon 59, through the second lumen 56.

A proximal connector assembly 62 is mounted on the proximal end PE of the catheter body 52. Such proximal connector assembly 62 has a side arm port 64 in communication with the second lumen 56 such that balloon inflation fluid may be injected or withdrawn through the side arm port 64 to cause alternate inflation and deflation of the balloon 59. Also, the proximal connector assembly 62 has a proximal port 66 through which any elongate member of suitable size and configuration, such as the imaging (IVUS) catheter, a passageway forming catheter 40, or other

catheters equipped for introducing channel connectors, channel sizers, lumen blockers, etc. as described in Applicant's earlier-filed United States Patent Application Serial Nos. 08/730,327 and 08/730,496, may be advanced  
5 through the first lumen 54 of the catheter body 52. The first lumen 54 of the catheter body 52 may be of a shape or configuration which is analogous to one or both of the catheters which are to be inserted through the first lumen 54 such that when such IVUS catheter, passageway forming  
10 catheter 70 or other elongate member 15 inserted into the first lumen 54, the outer surface(s) thereof will engage the inner surface of the first lumen 54 such that the IVUS catheter, passageway forming catheter 70 or other elongate member will be prevented from rotatably moving relative to  
15 the body of the catheter 52, and the operator will thereby maintain precise control over the rotational orientation of these apparatus. In particular, as shown in Figures 2b-2c, the first lumen 54 may have an inner luminal surface 64 of a "D" shape.

20 Referring to Figures 3a-3d, a particular passageway forming catheter 70 which is useable in conjunction with the anchorable guide catheter 50 may comprise a pliable catheter body 72 having at least a distal portion 74 having a generally D-shaped outer surface 76 which is of  
25 substantially the same size and configuration as the D-shaped luminal surface 64 of the first lumen 54. A tissue penetrating element 78 extends through the pliable catheter body 72 and is connected to a trigger 80 formed on the proximal hand piece 82 of the catheter device 70 such that,  
30 when the trigger 80 is actuated, the tissue penetrating element 78 will pass out of a side opening 80 formed in the D-shaped portion of the catheter body 72 such that the tissue penetrating element 78 will diverge laterally from the longitudinal axis LA of the catheter body 72, in this  
35 manner, the tissue penetrating element 78 may be utilized

to form an extravascular passageway which extends through the wall of the blood vessel into which the catheter 70 is inserted, to another blood vessel or other target location within the body.

5 Referring back to Figures 2a-2c', the anchorable guide catheter 50 is initially inserted into the vasculature and advanced to a position where the distal end DE of the balloon catheter body 52 and side opening 58 are located adjacent the location at which it is desired to form an  
10 extravascular passageway. An imaging catheter 80, such as an IVUS catheter, is inserted through the proximal port 66, and is advanced through the first lumen 54 until the imaging catheter 80 is in a position relative to the side opening 58 of the catheter body 52 to provide an image of  
15 anatomical structures located in alignment with such side opening 58. Thereafter, the guide catheter body 52 may be manually rotated until the image received through the imaging catheter 58 indicates that the opening 58 is directly aligned with the location at which the  
20 extravascular passageway is to be formed. In this regard, the catheter body 52 is of a torqueable construction, and may have the same dual-layer braided construction as described hereabove with respect to the torqueable sheath 10. In this manner, the anchorable guide catheter 50 may  
25 be manually rotated by the operator to effect precise rotational positioning of the opening 58 of the balloon anchorable guide catheter within the vasculature or other luminal anatomical structure within which the guide catheter 50 is inserted.

30 After the opening 58 of the balloon anchorable guide catheter 50 has been precisely rotationally positioned so that a passageway forming catheter 70 subsequently inserted through the guide catheter 50 will be appropriately aimed at the target anatomical location, the balloon 59 of the  
35 guide catheter 50 will be inflated (or the other pressure

exertive member will be actuated) to engage the surrounding luminal anatomical wall and to hold the distal portion of the guide catheter 50 in substantially fixed longitudinal and rotational position/orientation. In this regard, the material in which the balloon 59 is formed may be frictionally textured or coated with adhesive or otherwise modified with a friction producing outer surface to enhance its friction against the luminal wall. In this manner the balloon 59 will soundly engage the surrounding luminal wall to hold the distal portion of the guide catheter 50 in fixed position.

Thereafter, the imaging catheter 80 will be extracted from the first lumen 54, and a passageway-forming catheter such as that shown in Figures 3a-3d and described hereabove, will then be inserted through the lumen 54. The passageway forming catheter 70 may be advanced until the distal end DE of the passageway forming catheter body 72 abuts against the distal end surface 82 of the first lumen 54 of the guide catheter 50. When so inserted, the D-shaped outer surface 76 of the distal portion 74 of the passageway forming catheter body 72 will be in abutment with the D-shaped luminal surface 64 of the first lumen 54 of the guide catheter body 52, as shown in Figure 2c'. In instances where the proximal portion (i.e., that portion proximal to the distal portion 74) of the passageway forming catheter body 72 is not of the same D-shaped configuration, such proximal portion may simply reside within the D-shaped first lumen 54 in the manner shown in Figure 2b. Thus, it is not necessary that the entire length of the passageway-forming catheter body 72 have the D-shaped outer surface 76, but only that a distal portion 72 thereof have the D-shaped outer surface 76 so as to frictionally engage the D-shaped luminal surface 64 of the first lumen 54 in the manner shown.

Because the anchoring balloon 59 has been inflated,

the guide catheter body 52 will be prevented from rotating within the vasculature and will be held in a substantially fixed rotational orientation such that the side opening 58 is in direct alignment with the other blood vessel or target location to which the extravascular passageway is to extend. Thus, after the passageway-forming catheter 70 has been inserted into the first lumen 54 in the above-described manner, the triggering member 80 may be actuated to cause the tissue penetrating element 78 to pass out of the passageway forming catheter body 72, through the side opening 58 of the guide catheter, through the wall of the blood vessel in which the guide catheter 50 is located, and into another blood vessel or other extravascular target location. In some embodiments, the tissue penetrating element 78 may comprise a tubular member having a guidewire lumen 81 extending longitudinally therethrough. When such guidewire lumen 81 is present, a guidewire 79 may optionally be advanced through the tissue penetrating element 78 and into the other blood vessel or extravascular target location, after the tissue-penetrating element 78 has been advanced thereinto. After such guidewire 79 has been advanced into the other blood vessel or extravascular target location, the tissue penetrating element 78 may be retracted into the body of the passageway forming catheter 70, and the passageway forming catheter 70 and balloon anchorable guide catheter 50 may be extracted from the body, leaving the guidewire 79 in place to guide other devices or operative instruments through the newly created extravascular passageway.

iii. Passageway-Forming Catheter Device Having Torqueable Proximal Portion

Figures 4a-4e show another passageway-forming catheter device 100 of the present invention, which generally comprises an elongate catheter body 102 with definable proximal 104, medial 106 and distal 108 segments of varying

flexibility and torque strength.

The proximal segment 104 and medial segment 106 of the catheter body 102 incorporate reinforcement members, such as a reinforcement member braid 110, which will impart structural integrity to the proximal segment 104 and medial segment 106, and will enhance the ability of the proximal segment 104 and medial segment 106 to transmit torque from the proximal end of the catheter body 102. In some embodiments, the distal segment 108 may also incorporate such reinforcement members and/or braid 110. The reinforcement members and braid may be similar to or the same as that described in detail hereabove in reference to Figure 1.

As shown in Figure 4a, the proximal segment 104 may be of greater diameter than the medial segment 106. In this manner, the proximal segment 104 may comprise a cylindrical, dual lumen core member 140a of a first diameter  $D_1$  about which the reinforcement members or wire braid 110 are wrapped. An outer jacket 142a is then formed about the reinforcement members or wire braid 110, as shown in Figure 4b.

The mid-portion 106 comprises a cylindrical core member 140b of diameter  $D_2$ , about which the reinforcement members or wire braid 110 are wrapped. A cylindrical outer jacket 142b is also formed about the mid-portion 106 of the catheter body 102, and is continuous with the outer surface of the distal portion 108, as shown in Figure 4a.

It would be appreciated that the individual portions or members which make up each segment of 104, 106, 108 of the catheter body 102 may be formed of materials which have different physical properties (e.g., hardness, flexural properties, etc.) so as to bring about the desired regionalized variations in pliability and torque strength the catheter body 102. For example, in a presently preferred embodiment, the cylindrical core member 140a of

the proximal portion 104 is formed of a polymer material of a first hardness (e.g., Pebax of 63E Shore Hardness) and the cylindrical core member 140b of the mid-portion 106 is formed of a polymer material having a different hardness (e.g., Pebax of 40D Shore Hardness). The outer jacket 142a of the proximal portion 104 is formed of another polymeric material having yet a different hardness (e.g., Pebax 70D Shore Hardness) and the outer jacket 142d of the mid-portion 106 is formed of polymeric material having the same or similar hardness of that of the mid-portion 106 (e.g., Pebax of 40D Shore Hardness) other polymeric materials which may be used to form portions or members of the catheter body 102 include nylon, polyurethane, polyester, polyvinyl chloride (PVC) etc.

The catheter body 102 has a bottom portion BP and an upper portion UP. A curved or slanted frontal surface is formed on the distal end of the upper portion UP.

A first lumen 130 extends longitudinally through the catheter body from the proximal end to the distal end of the upper portion of the catheter body, and terminates distally at the distal outlet aperture 134.

A second lumen 132 also extends longitudinally through the catheter body from the proximal end thereof to a closed end wall or plug at the distal end of the lower portion LP of the catheter body 102. A proximal connector 136 is mounted on the proximal end of the catheter body. A proximal connector 136 has a proximal end port 134 and a side arm port 138. The proximal end port 134 is in communication with the first lumen 130 of the catheter body 102, and the side arm port 138 is in communication with the second lumen 132 of the catheter body 102. A tissue-penetrating element 150 extends through the first lumen 130. This tissue penetrating element 150 may be any suitable type of tissue penetrating element member, device, or flow of energy, as previously described in United States



Patent Application Serial No. 08/730,324, of which this application is a continuation-in-part. In embodiments wherein the tissue penetrating element 150 is an advanceable member or device, a handpiece of the type shown in Figure 3a-3b may be mounted on the proximal end port 134 such that the trigger 80 is connected to the tissue penetrating element 150 and is useable to alternately advance and retract the tissue penetrating element 150, out of/into the outlet aperture 134.

10 An imaging catheter, such as an intravascular ultrasound (IVUS) catheter may be inserted through one of the ports 134, 138 of the proximal connector 136 connected to the second lumen 132. In this manner the imaging catheter (IVUS) may be advanced through the second lumen 15 132 such that a distal portion of the imaging catheter extends into or out of and beyond the distal extent of the second lumen 132, thereby placing the imaging transducer or image receiving apparatus at a vantage point which is distal to the outlet aperture 134. Such imaging catheter 20 may then be utilized to image anatomical structures which are situated adjacent to in the vicinity of the outlet aperture 134, and to view the passage of the tissue-penetrating element 150 out of the outlet aperture 134 and through/into the adjacent anatomical structure.

25 iv. A Deflectable Catheter System for Forming Extraluminal Passageways

Figures 7-7b show another type of catheter system which may be utilized to form interstitial passageways between a luminal anatomical structure (e.g., a blood vessel) within which the catheter is positioned and another target anatomical location (e.g., another blood vessel, chamber of the heart, organ, tumor, etc.).

As shown in Figure 7, the system 1000 comprises a deflectable tipped catheter 110 which is useable in combination with an imaging catheter 112 (e.g., an IVUS

catheter) and a tissue penetrating element 114 (e.g., a sharp-tipped elongate member, or a flow of tissue-penetrating energy).

5 The deflectable tip catheter 110 comprises an elongate pliable catheter body 1016 having a deflectable distal end DE and a proximal end PE which is connected to a handpiece 1018.

10 A presently preferred construction of the handpiece 1118 is shown in Figure 7a, and a presently preferred construction of the distal end DE of the catheter body 1016 is shown in Figure 7b.

15 A working lumen 1020 extends longitudinally through the catheter body 1016 and through an opening 1022 in the distal end DE of the catheter body 1016. A secondary lumen 1026 extends longitudinally through the catheter body 1016, at an off center location along one side of the catheter body. Such secondary lumen 1026 terminates within the catheter body near the distal end thereof, and is thus a blind lumen. A pull wire 1024 extends longitudinally  
20 through the secondary lumen 1026 and the distal end 1028 of the pull wire 1024 is anchored or attached to the catheter body at a location within the catheter body, near the distal end thereof. The pull wire 1024 is axially moveable within the secondary lumen 1026 such that, when the pull  
25 wire 1024 is retracted in the proximal direction, it will cause the distal end DE of the catheter body 1016 to deflect in lateral direction, toward the side on which the secondary lumen 1026 is formed, as shown in Figure 7b.

30 The handpiece 1018 comprises a rear body portion 1030 and a forward body portion 1032 a knob 1034 is formed on the forward body portion 1032. The proximal end of the forward body portion 1032 is received within an inner bore 1036 of the rear body portion 1030 and is slidably retractable and advanceable within such bore 1036. A  
35 tubular member 1038 is positioned axially within the bore

136 of the rear body portion 1030 and extends through a portion of the forward body portion 132 as shown. This tube member 1038 is attached and anchored within the handpiece 1018 by way of a nut 1039. The catheter body 1016 extends through the tubular member 1038 and the proximal end PE of the catheter body 1016 is anchored within the rear body portion 1030, as shown. A slot 1040 is formed in the side of the tube member 1038. The pull wire 1014 extends through a small hole formed in the side of the catheter body 1016 within the forward body portion 1032 and through the slot 1040. The proximal end of the pull wire 1024 is attached to a set screw 1042 mounted in the side of the forward body portion 1032. An O-ring 1046 is mounted within an annular groove formed in the proximal portion of the forward body portion 1032 such that the O-ring will ride against the inner surface of the bore 1036 of the rear body portion 130 as the forward body portion 1032 is advanced and retracted therewithin.

In operation, when it is desired to cause the distal end DE of the catheter body 1016 to deflect laterally, the operator will grasp the knob 1034 of the forward body portion 1032 and will proximally retract the forward body portion 1032 into the bore 1036 of the rear body portion 1030, while the catheter body 1016 remains axially stationary due to its affixation to the proximal body portion 1030. In this manner, the pull wire 1024 will be proximally retracted within the secondary lumen 1026 and will cause the distal end DE of the catheter body 1016 to deflect in the desired lateral direction, as shown. Such deflection of the distal end DE of the catheter body 1016 may be utilized to cause the distal end outlet aperture 1022 to be specifically directed or aimed at the luminal wall of a luminal anatomical structure within which the catheter body 1016 is inserted.

A first frusto conical bore 1050 is formed within an

insert member 1052 located in the rear body portion 1030, and within which the proximal end PE of the catheter body 116 is extended. This frusto conical bore 1050 leads directly into the proximal end of the working lumen 1020 of the catheter body 1016 and will facilitate distally directed advancement of a guidewire, imaging catheter 1012, tissue penetrating element 1014, or other elongate apparatus through the main lumen 1020 of the catheter body 1016.

Another insert member 1054 having an opposite redirected frusto conical bore 1056 is also mounted within the bore 1036 of the rear body portion 1030, proximal to the first insert member 1052. This oppositely directed frusto conical bore 1056 will serve to guide and center the proximal end of a guidewire or similar elongate apparatus over which the catheter body 116 may be advanced such that it passes out of the proximal end PE of the catheter body 116.

Optionally, a hemostasis valve and/or gripping apparatus 1060 may be mounted on the proximal end of the rear body portion 130, immediately adjacent the proximal end opening 1062 of the bore 136 through which the guidewire(s), imaging catheter 1012, tissue penetrating element 1014 or other elongate apparatus may be passed.

In a preferred mode of operation, the catheter body 1016 is initially inserted into a luminal anatomical structure such that the distal end DE of the catheter body 1016 is located generally adjacent a site at which an interstitial passageway is to be formed through the wall of the luminal anatomical structure within which the catheter body 1016 is positioned. The imaging catheter 1012 (e.g., an IVUS catheter) is advanced through the proximal opening 1062, through the frusto conical bore 1050, and through the working lumen 1020 of the catheter body 1016 until the transducer or image-receiving element of the imaging

catheter 1012 is appropriately positioned to image the side wall of the luminal anatomical structure within which the catheter body 1016 is inserted and/or the target anatomical location to which the interstitial passageway is desired to extend. In many instances, this will require that a distal portion of the imaging catheter 1012 protrudes slightly out of and beyond the distal end opening 1022 of the working lumen 1020. With the image catheter 1012 in its operative position, it may be utilized to precisely locate the distal end DE of the catheter body 1016 in the desired longitudinal location and rotational orientation which will cause the distal end opening 1022 to be in alignment with the specific site on the wall of the luminal anatomical structure through which the passageway is to be formed. In this manner, one or more imageable markers or other aiming/positioning systems as described in this patent application or in applicant's related patent applications may be incorporated into the system 1000 to facilitate precise aiming and positioning of the distal end DE of the catheter body 1016.

After the distal end DE of the catheter body 1016 has been longitudinally and rotationally positioned/oriented, the imaging catheter 1012 will be extracted and removed, and the tissue-penetrating element 1014 will then be advanced through the proximal opening 1062, through the frusto conical bore 1050, and through the working lumen 1020 until the tissue-penetrating element is near the distal end opening 1022 but still contained within the working lumen 1020. Thereafter, the operator will grasp the knob 1034 of the handpiece 1018 and will retract the forward body portion 1032 of the handpiece rearwardly, into the rear body portion 1030. This will cause the pull wire 1024 to retract and will cause the distal end DE of the catheter to become laterally deflected such that the distal end opening 1022 is positioned in direct alignment with the

site on the wall of the luminal anatomical structure through which the passageway is to be formed. Thereafter, the tissue-penetrating element 1014 will be further advanced out of the distal end opening 1022 of the catheter body 1016, through the wall of the luminal anatomical structure, and through any intervening tissue, until the tissue-penetrating element 1012 emerges into the intended target anatomical location.

Thereafter, the tissue-penetrating element 1014 may be retracted through the working lumen 1020 and removed.

Thereafter, one or more secondary apparatus (e.g., channel connector delivery catheters, channel enlarging/modifying catheters, blocker catheters, etc.), may be advanced through the working lumen 1020 of the catheter to perform any desired modifications of the interstitial passageway or delivery of ancillary devices to facilitate flow of blood or biological fluids through the passageway, as desired.

Thereafter, when the procedure has been completed, the operator may again grasp the knob 1034 of the forward body portion 1032 and may distally advance the forward body portion to its original position, thereby allowing the distal end DE of the catheter body 1016 to return to its substantially straight, non-deflected configuration.

Those skilled in the art will appreciate that various modifications or changes may be made to the above-described system 1000 without departing from the intended spirit and scope of the invention. For example, although the preferred embodiment has been shown with a single working lumen 1020 extending through the deflectable catheter 1010, a plurality of such lumens may be formed to allow multiple components (e.g., the imaging catheter 112 and the tissue penetrating element 1014 and/or a guidewire (not shown)) to extend through the catheter body 1016 simultaneously. However, in many applications it will be desirably to

minimize the diameter of the catheter body 1016 and to maximize its pliability or flexibility, thereby rendering it desirable to utilize a single lumen 1020 in such applications.

5        Optionally, a side port 1057 may be formed in the rear body portion 1030 to permit infusion/withdrawal of fluid through the working lumen 1020 of the catheter 1000.

v.    Markers and Related Apparatus for Positioning/Aiming  
      The Passageway Forming Catheters

10        Figures 4d-6c show various markers and other apparatus which may be incorporated into any of the passageway forming catheters described in this patent application or any other suitable catheter, to provide a means for visually determining (e.g., by intracorporeal imaging such  
15    as intravascular ultrasound, or by extracorporeal imaging such as fluoroscopy) the precise positioning and rotational orientation of the distal portion of the catheter and/or for precisely aiming the tissue-penetrating element so that it will create the desired interstitial passageway as it is  
20    passed out of the passageway-forming catheter.

      In particular, Figures 4d-4e show markers which are particularly suitable for use on passageway-forming catheters which have a stepped or slanted distal end configuration, such as that of the torqueable catheters  
25    shown in Figure 4a. The remaining showings of Figures 4g-6c show markers and guidance/aiming apparatus which are useable with passageway-forming catheters which have various distal end configuration.

      Referring to Figure 4d, there is shown a distal  
30    portion of a passageway-forming catheter 100 hereupon a generally U-shaped marker 180 is mounted on the upper surface of the lower catheter body, distal to the tissue-penetrating outlet opening 134. The longitudinal midline of the marker 180 is in alignment with the path which will  
35    be followed by the tissue penetrating element 150 as it is

advanced out of the opening 134 in the catheter 100. In this manner, an imaging apparatus such as an IVUS catheter positioned within the lower catheter body portion at a vantage point distal to the distal end of the tissue-penetrating element outlet opening 134, may be utilized to ensure that the marker 180 is in direct alignment with the target tissue prior to advancement of the tissue-penetrating element 150 out of the opening 134.

Figure 4e shows a passageway forming catheter 100 having a marker strip 182 mounted on the upper portion of the lower catheter body, distal to the location of the tissue-penetrating element outlet opening 134. This marker strip 182 creates an image artifact which extends out radially to allow \*point\* in a specific direction which corresponds to the path of the tissue penetrating element. The longitudinal midline of this marker strip 182 is in alignment with the path which will be followed by the tissue-penetrating element 150 as it passes out of the opening 134. In this manner, an imaging apparatus such as an IVUS catheter positioned within the lower catheter body portion at a vantage point distal to the distal end of the tissue-penetrating element outlet opening 134, may be utilized to ensure that the marker strip 184 is in direct alignment with the target tissue, prior to advancement of the tissue penetrating element 150 out of the opening 134.

Figure 4f shows a wire marker 186 mounted on the distal portion of a passageway-forming catheter 100 which has an optional imaging window 101 formed in the lower catheter body, distal to the tissue-penetrating element outlet opening 134. The details of this imaging window were previously described in applicant's earlier-filed United States Patent Application Serial No. 08/730,496. The wire marker 186 comprises a single, elongate wire which is attached at its opposite ends, to the proximal and distal borders of the window 101. The elongate wire



marker 186 is preferably in the center of the window 101 and in alignment with the path which will be followed by the tissue penetrating element 150 as it is advanced out of the opening 134 in the catheter 100. In this manner, an  
5 imaging apparatus such as an IVUS catheter positioned within the lower catheter body portion so as to obtain an image through the imaging window 101, may be utilized to ensure that the marker wire 186 is in direct alignment with the target tissue prior to advancement of the tissue  
10 penetrating element 150 out of the opening 134.

Figure 4g shows another passageway-forming catheter 100' which has an imaging lumen 300 through which an imaging catheter may be advanced, and a working lumen 302 through which a tissue-penetrating element 150 may pass,  
15 such working lumen 302 terminating distally in an outlet opening 134 formed in the side of the catheter 100' at a spaced distance proximal to the distal end of the imaging lumen 300, as shown. A pliable distal tip member 189 is mounted on the distal end of the catheter 100', and the  
20 imaging lumen 300 extends through such tip member 189 and terminates in a distal opening formed therein. Additionally, a hollow passageway 191 extends longitudinally through such tip member 189 in direct alignment with the main portion of the working lumen 302.  
25 An imagable marking wire member 188, preferably formed of a combination of platinum and stainless steel, extends through the hollow passageway 191 in the tip member 189, and is surrounded laterally by a gap or space 193 within such passageway 191, as shown. The proximal end of this  
30 wire member 188 is embedded in a mass of imagable material 190 located within the body of the catheter 100'. Such mass of imagable material 190 is preferably a mixture of tungsten and a plastic (e.g., Pebax) or platinum. The distal end of the wire member 188 protrudes out of and  
35 beyond the distal end of the catheter body, as shown.

Figures 4h-4h' show another passageway-forming catheter 100'' comprising an elongate pliable catheter body having an imaging lumen 300 and a working lumen 302. An imaging apparatus, such as IVUS catheter, is advanceable  
5 through the imaging lumen 300. A tissue penetrating element (not shown) is passable through the working lumen 302 and out of the outlet aperture 134. A marker wire lumen 314 extends through a distal portion of the catheter 100'' between a proximal opening 316 formed in the upper  
10 wall of the imaging lumen 300, and a distal outlet aperture 318 formed in the distal end of the catheter 100'', above the distal end outlet 320 of the imaging lumen 300. A marker wire 310 is disposed within the imaging wire lumen 314. A proximal bulb 322 is formed on the proximal end of  
15 the marker wire 310, and an optional distal bulb 324 may be formed on the distal end thereof. Initially, the marker wire 310 is fully retracted into the marker wire lumen 314 such that its distal tip and any distal bulb 324 is wholly contained within the body of the catheter 100'', and with  
20 the proximal bulb 322 protruding slightly into the imaging lumen 300. The marker wire may be spring loaded or otherwise biased to this proximally retracted position. Thereafter, when an IVUS catheter is advanced through the imaging lumen 300, the distal end of the advancing IVUS  
25 catheter will drive the proximal bulb 322 of the marker wire 310 into a proximal cavity 326 formed at the proximal end of the marker wire lumen 314, thereby advancing the marker wire 310 such that a portion of the marker wire and its distal bulb 322 extends out of the distal end outlet  
30 aperture 318 and protrudes beyond the distal end of the catheter 100'', as shown in Figure 4h. The distal bulb 322 and a longitudinal axis of the marker wire 310 are in direct with the path which will be followed by a tissue-penetrating element (not shown) as it passes out of the  
35 outlet aperture 134. Thus, when the distal bulb 322 of the

distally advanced marker wire 310 is in direct alignment with the target tissue on the image received by the IVUS catheter, such will ensure that when the tissue penetrating element is advanced out the outlet aperture 134, it will be properly aimed and will advance into the target tissue, as desired.

Figures 4i and 4i' show another passageway-forming catheter 100''' having an imaging lumen which terminates in a distal outlet aperture 320 and a working lumen which terminates in a side outlet aperture 134. An imaging catheter, such as an IVUS is advanceable through the imaging lumen, and a tissue-penetrating element (not shown) is advanceable out of the side outlet aperture 134.

In the particular embodiment shown in Figure 4i, an arcuate wire marker 330 is mounted on the distal end of the catheter 100''', in a generally horizontal plane, above the distal out end outlet 320 of the imaging lumen 300. This arcuate wire marker 330 may be imaged by the transducer of an imaging catheter which protrudes out of the distal end outlet 320, and a specific, region of the artifact or image produced by the arcuate wire marker 330 may be fused, aimed or aligned with the target tissue, taking into account the distance between the catheter 100 and the target tissue, thereby ensuring that when the tissue penetrating element (not shown) is advanced out of aperture 134 it will extend into the intended target anatomical location or tissue.

In the alternative embodiment shown in Figure 4i', there is provided a 3-legged wire marker 332 mounted on the distal end of the catheter 100'''. Such 3-legged wire marker 332 comprises bottom legs 334 formed of single wire strands and an upper leg 336 formed of a single wire strand additionally having an outer wire coil formed therearound. The single wire strand and the outer wire coil may be formed of different materials. The upper leg 336 is in direct longitudinal alignment with the half which will be

followed by the tissue penetrating element as it passes out of the side outlet aperture 134 of the catheter 100'''. In this manner, when an imaging catheter such as an IVUS is advanced out of the distal end opening 320 of the imaging lumen, it may be utilized to directly align the upper leg 336 of the three-legged wire marker 322 with the intended target tissue, thereby insuring that when the tissue penetrating element is passed out of the side outlet aperture 134, it will form the desired passageway into the target tissue.

Figures 4j-4j' show a passageway forming catheter 100''' having the same configuration as that of Figures 4i-4i', but wherein a deflectable wire marker 340 is mounted on the end of the catheter 100''', as shown. Such deflectable wire marker 340 preferably comprises a single wire strand having an additional wire coil formed therearound. This deflectable wire marker 340 has a top end 342 which is attached to the body of the catheter 100''' at a site which is in direct longitudinal alignment with the side outlet aperture 134. When the deflectable wire marker 340 is in its non-deflected position (Figure 4j) its bottom end 344 will protrude downwardly over the distal end outlet 320 of the imaging lumen 300. Thus, when an imaging catheter such as an IVUS catheter is advanced through the imaging lumen 300 and out of the distal end outlet aperture 320 it will abut against the bottom portion of the deflectable wire marker 340, thereby causing the deflectable wire marker 340 to assume a deflected position as shown in Figures 4j'. When the deflectable wire marker 340 is in such deflected position, the longitudinal axis of the deflectable wire marker 340 will be in direct alignment with the path which will be followed by the tissue penetrating element (not shown) as it is passed out of the side outlet aperture 134. In this manner, the imaging catheter (IVUS) may be utilized to directly align the

longitudinal axis of the deflectable wire marker 340' with the target tissue, thereby insuring that when the tissue penetrating element is passed out of the side outlet aperture 134 it will form the desired interstitial passageway into the target tissue.

Figure 4k shows the same tissue-penetrating catheter 100''' wherein a secondary guidewire lumen 348 extends longitudinally through the body of the catheter 100'', from a proximal aperture 350 formed in the distal curved surface of the working lumen 302 to a distal guidewire outlet aperture 352 formed in the distal end of the catheter body, as shown. In this embodiment, the tissue penetrating element 150' comprises an elongate member having a sharpened distal end and a hollow guidewire lumen extending longitudinally therethrough. A guidewire 356 is advancable through the guidewire lumen of the tissue penetrating element 150'. When the tissue penetrating element 150 is retracted into the working lumen 302 as shown in Figure 4k, the guidewire 356 may be advanced out of the distal end of the tissue penetrating element 150, through the secondary guidewire lumen 348, wherein it will act as a marker which may be imaged by a imaging apparatus (e.g., an IVUS catheter) passed through the imaging lumen 300. The longitudinal axis of the guidewire 356, when positioned within the secondary guidewire lumen 348, will be in direct alignment with the path which will be followed by the tissue penetrating element 150 as it is advanced out of the side outlet aperture 134.

The showing of Figure 4k also incorporates a separate image-enhancing means whereby energy (e.g., ultrasonic vibration) may be imparted to the tissue penetrating element 150' as it is advanced out of the side outlet aperture 134 to render the distal portion of the tissue penetrating element 150' more easily visible by the imaging apparatus (e.g., IVUS catheter) positioned in the imaging

lumen 300. This is accomplished by an energy emitting member 370, such as an ultrasound generating device is mounted in the wall of the catheter 100'', about the side outlet aperture 134. A connector wire 372 extends  
5 longitudinally through the catheter 100'' to its proximal end, to permit the energy-emitting apparatus 370 to be connected to an appropriate source of energy. As the tissue penetrating element 150' is advanced out of the side outlet aperture 134, the energy emitting apparatus 370 is  
10 energized via the connector wire 372, thereby imparting energy to the distal portion of the tissue penetrating element and enhancing its visibility by the imaging apparatus positioned within the imaging lumen 300. One example of an ultrasound emitting chip which may be used as  
15 the energy emitting apparatus 370 such as a piezoelectric crystal of the type generally known in the art as a PZT crystal (lead-zirconate titanate).

Figure 4l shows a passageway-forming catheter 100'' of the same general configuration shown in Figures 4i-4k, but wherein at least a portion of the imaging lumen 300 is  
20 of non-round configuration. In the preferred embodiment shown, the imaging lumen 300 is of rectangular configuration having a longitudinal groove 373 extending along the upper surface thereof, as shown. A  
25 correspondingly shaped engagement member 378 is formed on the catheter 374 and such engagement member incorporates a longitudinal tongue 379 which fits slidably into the corresponding groove 373. In this manner, the catheter 374 can be inserted only in the desired rotational orientation,  
30 as shown. A phased array imaging catheter 374 having a phased array imaging transducer 376 mounted thereon is advanceable through the imaging lumen 300 of the catheter 100''. The irregularly shaped or non-round engagement member 378 formed on the outer surface of the phased array  
35 imaging catheter 374 and is configured to frictionally

engage the wall of the imaging lumen 300 to prevent the phased array imaging catheter 374 from rotating within the imaging lumen 300. An electronic marker is formed within the circuitry of the phased array imaging catheter 374 so as to mark a desired location L which is in direct alignment with the outlet aperture 134 of the catheter 100''' when the phased array imaging catheter 374 is non-rotatably inserted into the imaging lumen 300. In this manner, the electronically marked location L may be placed in direct alignment with the target tissue viewed on the image received through the phased array imaging catheter 374, thereby insuring that the outlet aperture 134 is also in alignment with the target tissue. It should be appreciated, that as an alternative to internally or electronically marking the desired location L on the phased array transducer 376, various imagable markers may be formed on the body of the catheter 100''' to mark the rotation of the outlet aperture 134, examples of such imagable markers being described hereabove and shown in Figure 4d-4k.

One example of an electrical system which may be utilized to electronically mark a desired location L on the image received from the phased array transducer 376 is shown, in schematic fashion, in Figure 4l'. With reference to Figure 4l and 4l', the phased array transducer 376 of the phased array imaging catheter 374 has a plurality of individual crystals 900 formed at spaced-apart locations on the transducer 376. Wires 902 extend from each of the individual crystals 900 of the phased array transducer 376, through the body of the phased array imaging catheter 374 and out of the proximal end thereof. One of these individual wires 902a is separated from remaining wires 902b, and the remaining wires 902b extend directly into a monitoring console 904 which produces the viewable image from the phased array transducer 376. The selected wire

902a is connected to a switch 906. When the switch 906 is in its open position, the signal received from the selected wire 902a will be shunted through a bypass circuit 908 which rejoins the remaining wires 902b prior to entry into the monitoring console 904. In this manner, when the switch 906 is open, the signal received from the selected wire 902a will bypass the signal modifying apparatus 903 and will rejoin the signals received from the remaining wires 902b to provide an image on the image monitoring console 904 which is unchanged and unmarked. However, when the switch 906 is closed, the signal received from the selected wire 902a will pass through a signal modifying apparatus 903. This signal modifying apparatus 903 may simply be an open switch which terminate the signal, thereby providing a void in place of the image which would be displayed from the individual crystal 900 from which the selected wire 902a extends. Alternatively, such signal modifying apparatus 903 may be a saturation apparatus which will produce white noise, or a color imparting apparatus which will tint or color the image received from the selected wire 902a. In either case, the image which subsequently appears on the image monitoring console 904 from the selected crystal 900 from which the selected wire 902a extends will be visually discernable by the operator and will provide a marking of the desired location L on the phased array imaging transducer 976.

Figures 4m and 4m' the presently preferred embodiment comprising a catheter 100'''' wherein a segment of the catheter body is cut away, with a plurality (e.g., (three (3)) struts 402, 404, 406 formed a connection between a proximal portion 408 of the catheter 100'''' and a distal portion 410 thereof, so as to form an imaging cage wherein the imaging catheter (e.g., IVUS) may be positioned. The top strut member 404 is of elongate configuration, and it longitudinal axis is directly aligned with the side outlet



aperture 134 through which the tissue penetrating element will pass. In this manner, when an imaging catheter is passed through the imaging lumen 300 such that its imaging transducer is located within or distal to the open area 400, such imaging catheter may be utilized to directly image the upper strut 404 and the catheter body 100'''' may be rotated until the upper strut 404 is in direct alignment with the image of the intended target tissue, thereby insuring that when the tissue penetrating element passes out of the side outlet aperture 134 it will form the desired interstitial passageway into the target tissue. Optionally, a pliable, hollow tip member 412 may be mounted on the distal end of the catheter 100'''''. In the embodiment shown in Figure 4m the optional tip member 412 is a frusto conical configuration, while in the embodiment of Figure 4m' the tip member 412' is of hemispherical configuration. It will be appreciated that this cage-like structure may be formed in many ways including by EDM technology or by forming the struts 402, 406, 408 of individual wires.

Any of the above-described markers shown in Figures 4d-4m' may incorporate regions thereon or discrete markings formed thereon, each such region or discrete marking being correlated to a specific range or distance from the catheter 100 to the anatomical target location. In this manner, the imaging apparatus (e.g., IVUS catheter) may be selectively used to align a specific region or distance-correlated marking on the marker with the target anatomical locations, based on the operator's knowledge, estimate or calculation of the range or distance from the catheter 100 to the target anatomical location. Additionally or alternatively, in embodiments wherein the imaging apparatus is mounted on a catheter which is insertable through an imaging lumen 300 in the passageway-forming catheter 100, the passageway forming catheter 100 may be provided with

length markings or friction-producing regions within the imaging lumen 300 to provide increased resistance or some other tactile sensation whereby the operator may judge the length of the imaging catheter (e.g., IVUS catheter) which  
5 has been advanced through the imaging lumen 300 and the present location of the imaging transducer or other image receiving apparatus thereon. In this manner, the operator may precisely position the imaging transducer or image receiving apparatus at a specific location (e.g., extended  
10 out of the distal end opening 320 and immediately distal to the distal end of the catheter 100) which provides the optimal vantage point for visualization of the target anatomical structure and marker, and for resultant aiming of the marker by rotational and longitudinal adjustment of  
15 the catheter 100.

Any of the imageable markers described herein, including but limited to those shown in Figures 4d-4m, may be formed of materials which affect the form of energy which is sensed by the imaging apparatus or catheter (e.g.,  
20 ultrasound being received by an IVUS catheter) to modify or enhance the artifact created by the marker. For example, any of these markers may be formed of material (e.g., soft plastic having low acoustic impedance) which is absorptive of the ultrasound or other energy form received by the  
25 imaging apparatus and, therefore, will appear as a void or black area on the image screen. Similarly, these markers may be formed of material (e.g., metals or alloys such as stainless steel, beryllium, or Nitinol) which is partially internally reflective of the energy form so as to give rise  
30 to an artifact (e.g., a streak or ray) which appears to emanate from in one or more directions from the exact location of the marker. In this manner, the marker may be positioned at a precise location and may be formed of material which is partially internally reflective such that  
35 an artifact (e.g., a ray or streak) is formed on the image

screen which directly correlates to the path which will be followed by the tissue-penetrating element, such artifact (e.g., ray or streak) being useful to enable the operator to determine the precise path which will be followed by the tissue penetrating element. In other applications, the marker may be formed of material which is reflective of the energy form such that a bright spot or exaggerated area will appear on the image screen when such marker is surrounded by tissue or other matter which is less than totally reflective of the energy form. Thus, in addition to the above-described methods for modifying the markers by applying energy (e.g., ultrasound) to the body of the marker, the exact form of the image or artifact produced by the marker may also be altered or optimized by forming the marker of a particular material of varied acoustic impedance, ranging from air or fluid filled cavities, to solid materials, to produce a range of marker effects on the image produced.

Figure 5 shows an alternative positioning-aiming system which is useable to facilitate precise positioning and aiming of the passageway forming catheter 100a. In this system, a signal emitting apparatus 500 is positioned in the target area (e.g., within a second blood vessel  $BV_2$ ) and a signal receiving apparatus 502 is mounted within the passageway-forming catheter 100a located within in a first blood vessel  $BV_1$ . The signal emitting apparatus 500 comprises a signal emitting wire 504 having a tubular shield 506 surrounding the shaft of the wire such that only a distal portion 508 of the wire 504 extends out of the distal end of the shielding tube 506. The shielding tube 506 may comprise any suitable electromagnetic shielding material, and is preferably formed of a pliable plastic tube having an aluminum braid formed therein. Those skilled in the art will appreciate that the signal emitting wire 504 may be attached to an extracorporeally located

signal generating apparatus capable of passing an electromagnetic signal through the wire 504. Such electromagnetic signal may be a 20 KHz signal.

5 The signal receiving apparatus 502 is preferably formed within the wall of the passageway forming catheter 100a laterally outboard of the working lumen 302 through which the tissue penetrating element is passed, and in direct alignment with the tissue penetrating element outlet aperture 134 formed in the side of the catheter 100a.  
10 Optionally, the catheter 100a may also include an imaging lumen 300 through which and imaging catheter (e.g., an IVUS catheter) may be passed. However, those skilled in the art will appreciate that in many applications the signal emitting apparatus 500 and signal receiving apparatus 502  
15 will be operable to control the precise positioning and rotational orientation of the catheter 100a, and such imaging lumen 300 may be unnecessary.

The signal receiving apparatus 502 formed in the passageway-forming catheter 100a comprises a signal  
20 receiving wire 510 having a tubular shielding apparatus 512 formed therearound. The tubular shielding apparatus 512 surrounds the shaft of the receiving wire 510 and a short distal portion 514 of the receiving wire 510 extends out of and beyond the distal end of the tubular shield 512. The  
25 tubular shield 512 may be formed in the same manner as the above-described tubular shield 506 of signal emitting apparatus 500. The exposed distal portion 514 of the signal receiving wire 510 is located immediately adjacent, and in longitudinal alignment with the side outlet aperture  
30 134. In this manner, an electro magnetic signal may be emitted through the signal emitting apparatus 500 after it has been positioned within the second blood vessel  $BV_2$  or other target tissue. The longitudinal positioning and rotational orientation of the passageway-forming catheter  
35 100a inserted within the first blood vessel  $BV_1$  may then be

adjusted until the signal received by the signal receiving apparatus 502 of the catheter 100a is at its peak intensity, thereby indicating that the exposed distal portion 514 of the receiving wire 510 has been positioned  
5 at its closest possible point to the exposed distal portion 508 of the signal emitting wire 504. This will ensure that the passageway forming catheter 100a is longitudinally positioned at the closest straight-lined point from the signal emitting apparatus 500 located within the second  
10 blood vessel BV<sub>2</sub> or other target tissue, and that the catheter 100a has been rotated to a rotational orientation wherein the outlet aperture 134 is directly aimed at the signal emitting apparatus 500 located within the second blood vessel BV<sub>2</sub> or other target tissue. It will be further  
15 appreciated by those skilled in the art that various types of energy-emitting signals may be utilized into, such that the signal emitting apparatus 500 located within the second blood vessel BV<sub>2</sub> or target tissue is an "active" element and the signal receiving apparatus 502 associated with the  
20 passageway forming catheter 100a is a "passive" or receiving element. The types of signals which may be utilized include, but are not necessarily limited to, electromagnetic signals (as specifically described hereabove), sonic signals (e.g., doppler), ultrasonic  
25 signals, high intensity light, laser, radiofrequency, etc.

Figure 5a shows another positioning/aiming system which is wholly incorporated into the passageway-forming catheter 100b. A signal emitting or "active" component 520, such as a piezoelectric crystal is mounted upon or  
30 formed within the catheter 100b so to emit a signal or flow of energy which will strike, enter or be reflected from the target tissue T. A passive or receiving apparatus, such as another piezoelectric crystal may be mounted at a second location within or upon the catheter 100d so as to receive  
35 a reflected signal or returning signal from the target

tissue T. The position of the passive or receiving apparatus 522 relative to the active or emitting apparatus 520 is known, and may be utilized to precisely determine the longitudinal position and rotation orientation of the catheter 100b. In this manner, this positioning/aiming system may be utilized to effect precise longitudinal positioning and rotational orientation of the catheter such that when the tissue penetrating element is passed out of the outlet aperture 134, it will extend into the target tissue T, as desired. Those skilled in the art will appreciate that, as an alternative to the passive receiving apparatus 522, or in addition thereto, an optional imaging lumen 300 may extend through the body of the catheter 100b such that an imaging catheter (e.g., IVUS catheter or receiving catheter carrying the passive receiving apparatus 522 may be passed through such lumen 300 and utilized to alternatively or additionally facilitate the positioning and rotational orientation of the catheter 100b.

Figure 5b shows yet another alternative positioning/aiming system wherein a signal emitting crystal 530 is positioned on or within the catheter 100c so as to emit a signal (e.g., ultrasound or sound waves) in a direction which is specifically aligned with the path which will be followed by the tissue penetrating element as it passes out of the side outlet aperture 134 an imaging catheter. An imaging catheter (e.g., an IVUS catheter) positioned within the imaging lumen 300 is utilized to receive the signal from the crystal 530 after it has reflected from the target tissue T, thereby discerning the specific point of impingement X on the target tissue T where it is struck by the energy being emitted by the signal emitting crystal 530. In this manner, the imaging catheter positioned within the imaging lumen 300 may be utilized, to precisely position and aim the outlet aperture 134 of the passageway-forming catheter at the energy

impingement point X on the target tissue T, thereby insuring that, when the tissue penetrating element is advanced out of the outlet aperture 134, it will extend into the target tissue T at a desired site.

5 Further referring to Figure 5b, the signal emitting crystal 530 may be alternatively utilized as a signal receiving crystal, such that it will receive reflected ultrasound from the IVUS, as indicated by the dotted arrows on Figure 5b. Since the signal receiving crystal 530 is  
10 specifically positioned and oriented in relation to the outlet 134 and/or path of the tissue penetrating element 150, such receipt of the IVUS ultrasound by the signal receiving crystal 530 will enable the operator to precisely position and rotationally orient the catheter such that the  
15 tissue penetrating element 150 will pass directly into the target tissue T, in parallel to the path of reflected ultrasound received by the signal receiving crystal 530.

Figure 5c shows yet another positioning/aiming system wherein the passageway-forming catheter 100d has a working  
20 lumen 302 which terminates in a side outlet aperture 134 and through which a tissue-penetrating element 500 in the nature of an elongate member 540 having a sharpened distal end may be advanced through such working lumen 302 and out of the side outlet aperture 134 of the catheter 100d. The  
25 elongate member 540 in this embodiment is equipped with a sensor apparatus 548 positioned at or near the sharpened distal end of the elongate member 540. A connector wire 550 may extend longitudinally through the elongate member 540 to permit the sensor 548 to send a signal through the  
30 shaft of the member 540 to an extracorporeal location at which such signal may be processed and/or monitored. The sensor 548 may be any suitable type of sensor which will sense the presence and/or location of the intended target tissue T. Parameters or variables which may be sensed by  
35 the sensor 548 include temperature, pulse, flow, or other

characteristics of the target tissue T, capable of being mechanically, electronically or optically sensed. Additionally or alternatively, an energy emitting or "active" apparatus, such as the energy emitting apparatus 5 500 described hereabove with reference to Figure 5, may be positioned within the target tissue T and the sensor 548 formed on the tissue penetrating member 540 may be adapted to receive and sense energy emitted by the active energy emitting member located within the target tissue T. In 10 this manner, the tissue penetrating member 540 serves its own sensing function and enables the operator to control the longitudinal and rotational position of the catheter 100d prior to or during the advancement of the tissue penetrating member 540 out of the outlet aperture 134 and 15 into the target tissue T. It will be appreciated by those skilled in the art, when a tissue penetrating member 540 having an onboard sensor 548 of the type described herein is utilized, such will eliminate the need for any other extracorporeal or intracorporeal imaging or sensing 20 apparatus for aiding in positioning or rotational orientation of the catheter 100b. Alternatively, the catheter 100b may also be provided with other onboard aiming/positioning apparatus or an imaging lumen 300 as described in reference to various other embodiments shown 25 in Figures 4-5.

Figure 5d shows another aiming/positioning system which is similar to that shown in Figure 5b, but wherein the emitting member 530 (e.g., an ultrasound emitting piezoelectric crystal) is aimed downwardly at the 30 transducer or receiving port of the imaging catheter (e.g., IVUS catheter), and the emitting member 530 is specifically positioned relative to the outlet opening 134 so as to provide an imageable marking at the outlet opening 134. In this manner, the imaging catheter (IVUS catheter) may be 35 used to specifically site and identify the location of the



outlet aperture 134, thereby facilitating longitudinal positioning and rotational aiming of the catheter prior to deployment of the tissue penetrating member 150.

Figure 5e shows one embodiment of a system 790 which  
5 may be utilized to facilitate optimization or peaking of the signal received from a sensor or receiving component which is utilized to position and aim the catheter, such as those described hereabove and identified by reference numerals 502, 522, 530 and 548. In this system 790, the  
10 wire 510, 521, 531, 550 through which a signal is received from the receiving component 502, 522, 530, 548 is connected to a switch 818. When the switch 818 is open, the signal received will not enter the system 790. However, when the switch 818 is closed, the signal received  
15 from the receiving or sensing component 502, 522, 530, 548 will enter a signal conditioning and filtering component 880 wherein the signal will undergo conditioning and filtering. Thereafter this signal will pass through a rectifier 810 wherein the signal will be rectified, and  
20 through a leaky integrator 812 of the type well known in the art. Such leaky integrator 812 may comprise a capacitor and a resistor in parallel. The integrated signal from the leaky integrator 812 may then pass into an analog to digital convertor 814, if desired, whereby it  
25 will be converted to a digital signal, and such digital signal will then be fed to a display 816 of a type suitable for indicating the relative intensity of the signal received. Such display may be an LED or multiple light display, whereby a column or array of lights are provided  
30 and the intensity of the signal received is indicated by the height of the column or the number of lights in the array which are lit at any given time.

In this manner, the system 790 shown in Figure 5d may be utilized to enable the operator to longitudinally and  
35 rotationally move the catheter until the signal received

from the receiving component or sensor 502, 522, 530, 548 has been peaked or optimized, thereby indicating that the catheter is properly positioned such that the tissue penetrating element will extend from the outlet 130 into the target anatomical location T.

Figures 6-6c show other catheter marking schemes which may be used in conjunction with an extracorporeal imaging apparatus 118, such as a fluoroscope, positioned adjacent a mammalian body MB. In the showing of Figure 6, a catheter 100 has been advanced into the blood vessel  $BV_1$ , and such catheter is marked with one of the marking schemes of this embodiment of the present invention. Figures 6a-6c show the manner in which the marking scheme of the catheter 100 will appear on the fluoroscopy screen 120 as the catheter is rotated within the blood vessel  $BV_1$ .

Referring to Figure 6a, there is provided a marking scheme which comprises a first radio-opaque linear marking 122 on one side of the catheter body, and a second radio-opaque linear marking 122b. The second linear marking 122b is located directly and  $180^\circ$  opposite the first linear marking 122a, but slightly more distal to the first marking 122a. An additional rotation indicating indicia 200, comprising the letter "R" formed of radio-opaque or other imagable material, is formed to the right of the first linear marking 122a. As shown in Figure 6a, when the catheter is in its desired rotational orientation, the first and second linear markings 122a and 122b will appear next to and in linear alignment with one another on the fluoroscopy screen 120. When such markings 122a and 122b are viewed from the right side RS of the catheter body the rotational marking indicia 200 will appear as the letter "R". However, when the catheter is rotated  $180^\circ$  such that the fluoroscope 118 views the catheter from the left side LS of the catheter body, the rotational marking indicia 200 will appear as the inverted mirror image of the letter "R",

thereby informing the operator that the catheter is rotated 180° from the desired rotational orientation.

Figure 6b shows a similar marking scheme wherein the rotational marking indicia 200 is formed adjacent a radio-opaque circle 24 formed on the right side RS of the catheter body such that, when the catheter body is in its desired rotational position, a radio-opaque dot 126 formed on the left side LS of the catheter body will appear within the circle 124 on the fluoroscopy screen 120, and the rotational marking indicia 200 will appear as the letter "R" to the right of the radio-opaque circle 124. However, when the catheter body is rotated 180° such that the fluoroscope 118 is viewing the left side LS of the catheter body, the rotational marking indicia 200 will appear as the inverted mirror image of the letter "R" on the left side of the circular marking indicia 124, as illustrated in Figure 6b.

Similarly, as shown in Figure 6c, the catheter 100 may be provided with two (2) through holes 128a, 128b formed in direct linear alignment with one another on opposite sides of the catheter 100. Adjacent one of the through holes is an imageable marker in the form of the letter "R". When the catheter 100 is rotated such that the through holes 128a, 128b are in direct alignment with the extracorporeal imaging apparatus 118, both through holes 128a, 128b will appear as a single aperture on the image provided on the image viewing apparatus 120. However, when the through holes 128a, 128b are not in direct alignment with one another, they will appear as separate images on the image viewing apparatus 120. In this manner, these through holes 128a, 128b may be utilized to discern the correct rotational orientation of the catheter using an extracorporeal imaging apparatus 118. Similarly, as described hereabove, the letter R will appear differently depending on which side of the catheter 100 is closest to

the imaging apparatus 118, thereby avoiding any possible inadvertent 180° mis-rotation of the catheter.

vi. Apparatus For Preventing Inadvertent Deployment of  
5 Tissue Penetrating Element

Figure 8 shows another embodiment of the catheter 100e which incorporates apparatus for preventing inadvertent deployment of the tissue-penetrating element 150. In this catheter 100e, a lumen closure member 548 is pivotally  
10 mounted on one side of the working lumen 302 through which the tissue penetrating element 150 will pass such that, when in an upwardly pivoted position, such member 548 will block the lumen and prevent inadvertent advancement of the tissue penetrating element out of the opening 134. A  
15 balloon 544 or other pressure exerting member is mounted within the body of the catheter 100e, adjacent the blocking member 548 in the embodiment shown, a balloon inflation lumen 546 extends through the catheter to permit alternate inflation and deflation of the balloon. In this manner,  
20 when the balloon 544 is inflated, as shown in Figure 8, the member 548 will pivot upwardly so as to block the working lumen 302 in a manner which will prevent inadvertent deployment of the tissue penetrating element 150. Alternately, when the balloon 544 is deflated, the member  
25 548 will pivot downwardly thereby restoring the working lumen 302 to an open configuration through which the tissue-penetrating element 150 may pass.

Figure 8' shows another embodiment of the catheter 100e which incorporates apparatus for stabilizing the  
30 catheter within a vessel after proper orientation has been confirmed. This apparatus also prevents inadvertent deployment of the tissue penetrating element 150 in combination with the stabilization. In this catheter 100e, a lumen closure member 548' is pivotally mounted near the  
35 working lumen 302 through which the tissue penetrating

element 150 will pass. The lumen closure member 548' is biased or spring loaded by spring member 998 such that when the balloon, 544' or other pressure exerting member is deflated, lumen 302 is blocked preventing inadvertent advancement of the tissue penetrating element out of the opening 134. A balloon inflation lumen 546 extends through the catheter to permit alternate inflation and deflation of the balloon. After proper orientation of the catheter 100e has been confirmed, the balloon is inflated which causes a portion of the balloon to exit the side of the catheter through exit port 999 which secures the catheter in place within the vessel, 997 as is shown in Figure 8''. Simultaneous with anchoring the catheter in place, inflation of the balloon causes lumen closure member 548' to pivot thereby opening the working lumen 302 to allow advancement of the tissue penetrating element 150.

Materials, construction and treatments of the balloon, 544' may be made to prevent undesired movement or dislodgment in the vessel during its inflated state. Treatment may include surface modification, Dacron, or other means.

It should be appreciated that the general concept of combining an anchoring device which is deployed after confirmation of proper orientation of the tissue penetrating element which simultaneously or nearly thereafter, removes a safety device previously in place to prevent inadvertent advancement of the tissue penetrating element, can be accomplished in other ways not completely described above.

It will be appreciated by those skilled in the art that the invention has been described hereabove with reference to certain presently preferred embodiments and examples only, and no effort has been made to exhaustively describe all possible embodiments and examples in which the invention may take physical form. Furthermore, it will be

appreciated that each of the specific components and elements of the above-described embodiments and examples may be combined or used in conjunction with any of the other components shown in relation to other embodiments or  
5 examples, to the extent such recombination of elements or components may be accomplished without rendering the device, apparatus, or system unusable for its intended purpose. Furthermore, various additions, deletions, modifications, and alterations may be made to the above-  
10 described embodiments and examples without departing from the intended spirit and scope of the invention. Accordingly it is intended that all such variations, recombination, additions, deletions and modifications be included within the scope of the following claims.

15

WHAT IS CLAIMED IS:

1. A torqueable sheath which is insertable into a mammalian body and useable to rotationally position of the distal end of a catheter which has been inserted through  
5 the sheath; said sheath comprising:

a pliable tubular sheath body having a proximal end, a distal end and a hollow lumen extending longitudinally therethrough, said tubular sheath body having sufficient torque strength to transfer torque  
10 from the proximal end thereof to the distal end thereof, such that the distal end of the sheath body will rotate in substantial correlation with the proximal end of the sheath body;

a catheter engaging surface formed within the  
15 lumen of the sheath body, said catheter engaging surface being operative to engage the catheter when the catheter has been inserted through the sheath, such that i) the catheter will be prevented from rotating independently of the introducer sheath, but  
20 ii) at least the distal end of the catheter will be caused to rotate in unison with the sheath.

2. The torqueable sheath of Claim 1 wherein said tubular sheath body is formed of a polymeric material having reinforcement members disposed therein to increase  
25 the torque strength of said polymeric material.

3. The torqueable sheath of Claim 2 wherein said reinforcement members are formed into a braid.

4. The torqueable sheath of Claim 3 wherein said braid is formed of first and second groups of elongate  
30 members, each of said groups of elongate members being made up of a plurality of individual elongate members arranged in substantially parallel, side-by-side relation to one another, said first group being wound about the lumen of the sheath body in a clockwise direction, and said second  
35 group being helically wound about the lumen of the sheath

body in a counterclockwise direction, such that the elongate members of the first group cross with the elongate members of the second group at a plurality of cross-over locations, the individual elongate members of the first group being alternately passed over and under the individual elongate members of the second group at said cross-over locations, so as to form a tubular braid about the lumen of said sheath body.

5. An anchorable guide catheter which is insertable into a luminal anatomical structure, said guide catheter comprising:

a elongate catheter body having at least one lumen extending longitudinally therethrough;

an opening formed at a first location in said catheter body, in communications with said at least one lumen;

a pressure exerting member formed on said catheter body, said pressure exerting member being engageable with the luminal anatomical structure to prevent the first location of the catheter body from moving within the luminal anatomical structure.

6. The anchorable guide catheter of Claim 5 wherein said pressure exerting member is a balloon, and wherein said balloon is inflatable such that it will engage the luminal anatomical structure to prevent the first location of the catheter from moving within said luminal anatomical structure.

7. The anchorable guide catheter of Claim 6 wherein said balloon includes a friction enhancing treatment upon a surface of the balloon which engages the luminal anatomical structure.

8. The anchorable guide catheter of Claim 7 wherein said friction enhancing treatment on said balloon is selected from the group of friction enhancing treatments consisting of:



texturing;  
adhesive; and,  
woven fabric.

9. The anchorable guide catheter of Claim 5 further  
5 comprising:

at least one engagement surface associated with  
said first lumen, said at least one engagement surface  
being operative to engage a second catheter which has  
been inserted through said first lumen such that said  
10 second catheter is thereby prevented from rotating  
independently of said balloon-anchorable guide  
catheter.

7. The anchorable guide catheter of Claim 9 in  
combination with at least a) an imaging catheter and b) a  
15 passageway-forming catheter having a tissue-penetrating  
element which is passable through the wall of the luminal  
anatomical structure within which the balloon-anchorable  
guide catheter is positioned, said anchorable guide  
catheter being useable in conjunction with said imaging  
20 catheter and said passageway-forming catheter to form said  
passageway through the wall of the luminal anatomical  
structure, at a predetermined location, by the following  
steps:

i) transluminally advancing the guide catheter  
25 into said luminal anatomical structure until the  
opening of the guide catheter is near the location on  
the luminal anatomical structure through which said  
passageway is to be formed;

ii) inserting the imaging catheter into a lumen  
30 of the guide catheter such that the imaging catheter  
will image anatomical structures which are in  
alignment with the opening of the guide catheter;

iii) moving the guide catheter until the image  
obtained by the imaging catheter indicates that the  
35 opening of the guide catheter is in alignment with the

site at which the extravascular passageway is to be formed;

5           iv) causing the pressure exerting member to engage the luminal anatomical structure 10 as to hold the first location of the guide catheter in substantially fixed position;

          v) removing the imaging catheter from the first lumen of the guide catheter;

10           vi) inserting the passageway-forming catheter into a lumen of the guide catheter such that the passageway-forming catheter engages the at least one engagement surface of the guide catheter;

15           vii) causing the tissue-penetrating element to pass out of the passageway-forming catheter, through the opening of the guide catheter, and through the wall of the luminal anatomical structure, thereby forming said passageway.

8.    The anchorable guide catheter of Claim 7 wherein the pressure exerting member is an inflatable balloon, and  
20    wherein the step iv) comprises inflating the balloon such that the balloon will engage the luminal anatomical structure.

9.    In a passageway-forming catheter of the type having i) an elongate catheter body and ii) a tissue-penetrating element which is advanceable out of a first  
25    location on the elongate catheter body so as to pass through the wall of a luminal anatomical structure and to a target location in which said catheter is positioned, and iii) an imaging means which is useable to image the target  
30    location, the improvement comprising:

          a marker formed on said catheter at a second location, said second location being positioned relative to said imaging means and said first location, such that when the position and rotational  
35    orientation of the catheter is adjusted such that said

marker is aimed at said target location, said tissue penetrating element will penetrate through the wall of the luminal structure and into said target location.

10. The catheter of Claim 9 wherein said marker  
5 comprises:

a U-shaped member mounted on said catheter.

11. The catheter of Claim 9 wherein said marker  
comprises:

10 an elongate, generally rectangular member mounted  
on said catheter.

12. The catheter of Claim 9 wherein said marker  
comprises:

a elongate wire mounted on said catheter.

13. The catheter of Claim 9 wherein said marker  
15 comprises an arcuate member attached to and extending  
distally from the distal end of the catheter body, said  
arcuate member being disposed in a plane which is  
substantially perpendicular to the path of the tissue-  
penetrating element.

20 14. The catheter of Claim 9 wherein said marker  
comprises a tripod member mounted on the distal end of the  
catheter, said tripod member having first second and third  
legs attached to said catheter and to one another, at least  
one of said legs being in alignment with the path of the  
25 tissue penetrating element.

15. The catheter of Claim 9 wherein the imaging means  
comprises an elongate imaging lumen which extends  
longitudinally through the catheter body and into which an  
imaging apparatus is insertable and positionable so as to  
30 obtain an image of said marker and said target anatomical  
structure.

16. The catheter of Claim 15 wherein said imaging  
lumen extends longitudinally through the catheter and opens  
through an outlet aperture in the distal end of the  
35 catheter, and wherein said imaging apparatus is advanceable

through said lumen such that the imaging apparatus protrudes out of and extends beyond the distal end of the catheter.

17. The catheter of Claim 15 wherein said imaging  
5 lumen extends longitudinally through said catheter and wherein an imaging window is formed at a second location on said catheter such that an imaging apparatus may be advanced through said imaging lumen and utilized to obtain an image of said marker and said target anatomical  
10 structure, through said imaging window.

18. The catheter of Claim 9 wherein said catheter further comprises:

a flexible tip member mounted on the distal end of the catheter, said flexible tip member having a  
15 hollow passageway extending longitudinally therethrough, and wherein said marker comprises an elongate member attached to said catheter body and extending through at least a portion of the hollow passageway formed in said elongate member.

20 19. The catheter of Claim 18 wherein said hollow passageway has a first diameter, and wherein said elongate member has a second diameter smaller than said first diameter, such that a gap surrounds said elongate member within said hollow passageway.

25 20. The catheter of Claim 18 wherein said elongate member protrudes beyond the distal end of said distal tip member.

21. The catheter of Claim 9 wherein said marker comprises:

30 a notch formed within said catheter and surrounded by a plurality of strut members, said imaging means being positionable within said notch, and at least one of said strut members being useable as said marker.

35 22. The catheter of Claim 21 wherein said strut

members comprise elongate wires attached to said catheter body and extending over said notch.

23. The catheter of Claim 21 wherein said notch comprises a region which is cut away from said catheter body such that there is defined a proximal catheter body portion proximal to said notch, and a distal catheter body portion distal to said notch.

24. The catheter of Claim 23 wherein an imaging catheter lumen extends longitudinally through said catheter body, and wherein said imaging means comprises an imaging catheter which is advanceable through said imaging catheter lumen and into said notch such that the image received by said imaging catheter includes the image of said at least one strut member which is useable as said marker.

25. The passageway-forming catheter of Claim 9 wherein said marker is a signal-emitting component which emits a signal which may be detected by said imaging means.

26. The passageway-forming catheter of Claim 25 wherein said energy-emitting component is a piezoelectric crystal.

27. The catheter of Claim 9 wherein the distance from said first location on said catheter to said target anatomical structure is known, and wherein said marker further comprises:

a plurality of distance-specific marker locations, each said distance-specific marker location being correlated to a known distance from said first location on said catheter to said target anatomical structure, said imaging means being thereby useable to position a selected one of said distance-correlated markings in alignment with the image of said target anatomical structure, thereby placing the catheter in optimal position and orientation to cause said tissue-penetrating element to form the desired passageway to

said target anatomical structure, without extending beyond said target anatomical structure.

28. A system for positioning/aiming a passageway forming catheter which comprises an elongate catheter body  
5 having a tissue-penetrating element passable out of said catheter body in a lateral direction so as to create an interstitial passageway through the wall of the luminal anatomical structure within which the catheter is inserted into a target anatomical location, said apparatus  
10 comprising:

an emitting component which causes a signal to be emitted from said target anatomical location; and,

a receiving component which receives said signal from said anatomical location;

15 one of said emitting and receiving components being located at a fixed position relative to the path which will be followed by said tissue penetrating element as said tissue penetrating element passes out of said catheter, and being thereby useable to  
20 position and orient said catheter such that said tissue-penetrating element will create the desired interstitial passageway into said target anatomical location.

29. The system of Claim 28 wherein said emitting  
25 component and said receiving component are both located on said passageway-forming catheter.

30. The system of Claim 28 wherein one of said emitting component and said receiving component is located at said target anatomical location, and the other thereof  
30 is located on said passageway-forming catheter.

31. The system of Claim 28 wherein said emitting component comprises an energy-emitting member which emits a form of energy selected from the group of energy forms consisting of:

35 sonic energy;

ultrasonic energy;  
light energy;  
laser light energy;  
radio frequency energy;

5           an electromagnetic signal;

and wherein said receiving component comprises a sensor adapted to receive said form of energy.

32. The system of Claim 28 wherein said emitting and receiving components are respectively positioned such that,  
10   when said emitting and receiving components are brought into direct alignment to direct alignment with one another, the passageway-forming catheter will be properly positioned to cause said tissue-penetrating element to pass from said passageway to forming catheter into said target anatomical  
15   location, and wherein said system further comprises:

apparatus for monitoring the intensity of the signal received by the receiving component, such that one may determine when the signal received by the receiving component has been peaked, thereby  
20   indicating that the emitting and receiving components have been brought into direct alignment with one another and the catheter is correctly positioned and oriented.

33. The system of Claim 32 wherein said apparatus for  
25   monitoring the intensity of the signal received by the receiving component comprises in series:

a signal conditioning and filtering component;  
a rectifier;  
a leaky integrator;  
30   a analog to digital converter; and,  
a display adapted to display the strength of the signal received by the receiving component.

34. The system of Claim 28 wherein said emitting component comprises an elongate pliable wire having an  
35   emission-preventing shield formed laterally about the

length of the wire, with the distal tip of the wire extending out of and beyond said shield such that energy may be emitted by only the distal tip of the wire.

35. The system of Claim 28 adapted for use in a procedure wherein the passageway-forming catheter is transluminally advanced into a first blood vessel for the purpose of forming a passageway through the wall of said first blood vessel and into said target anatomical location, and wherein one of said emitting and receiving components is insertable into said target anatomical location and the other thereof is mounted on said passageway-forming catheter.

36. A system for forming an interstitial passageway which extends through the wall of a luminal anatomical structure, said system comprising:

a) a deflectable catheter having an elongate pliable catheter body, a distal end, at least one lumen extending longitudinally through the catheter body, and a distal end opening through which said lumen opens at the distal end of said catheter body, a portion of said catheter body immediately adjacent the distal end thereof being alternately moveable between:

i) a straight configuration; and,  
ii) a curved configuration;

b) an imaging apparatus which is insertable through at least a portion of said at least one lumen of said deflectable catheter to provide an image of at least the luminal anatomical structure when said deflectable catheter is inserted into said luminal anatomical structure; and,

c) a tissue-penetrating element which is advanceable through said at least one lumen of said catheter and out of said distal end opening such that, when the distal portion of the catheter is in its



curved configuration within said luminal anatomical structure, the tissue-penetrating element will pass out of said distal end opening and through the wall of said luminal anatomical structure.

5        37. The system of Claim 36 wherein said catheter further comprises:

10            a marker formed on said catheter at a first location, said marker being positioned at a known location on said catheter and being imagable by said  
15            imaging apparatus when said imaging apparatus is inserted into said at least one lumen of said catheter, said marker being thereby useable to facilitate selected rotation orientation of said catheter within said luminal anatomical structure such  
20            that, when the distal portion of the catheter is moved to its curved configuration, the distal opening of the catheter will be aimed at a desired location on said luminal anatomical structure.

25        38. The system of Claim 36 wherein said system further comprises:

30            d) a passageway modifying apparatus which is passable through said at least one lumen of said catheter and out of said distal opening, said passageway modifying apparatus being useable to modify  
35            a passageway which has been initially formed by said tissue-penetrating element.

39. The system of Claim 38 wherein said passageway modifying apparatus is selected from the group of passageway modifying apparatus consisting of:

30            an apparatus for closing said passageway;  
             an apparatus for stenting said passageway;  
             an apparatus for enlarging said passageway;  
             an apparatus for cauterizing said passageway;  
             an apparatus for placing a channel connector  
35            within said passageway;

an apparatus for blocking the lumen of an anatomized conduit on either side of said passageway to effect flow through said passageway.

40. The catheter of Claim 9 wherein the marker is  
5 formed of material which is reflective of energy which is received by the imaging means for the purpose of forming the image.

41. The catheter of Claim 9 wherein the marker is  
10 formed of material which is partially internally reflective of energy which is received by the imaging means for the purpose of forming the image.

42. The catheter of Claim 9 wherein the marker is  
15 formed of material which is absorptive of energy which is received by the imaging means for the purpose of forming the image.

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Abstract

The inventions described in this patent application include i) a torqueable introducer sheath which is useable in conjunction with a transvascular passageway forming catheter to effect precise rotational control of the catheter; ii) an anchorable guide catheter which is useable in conjunction with an intravascular imaging catheter and a transvascular passageway-forming catheter to effect precise positioning and aiming of the passageway-forming catheter; iii) a passageway forming catheter having a torqueable proximal portion to facilitate precise rotational positioning of the distal portion of the catheter; iv) a deflectable-tipped passageway forming catheter, v) various markers and other apparatus useable in conjunction with any of the passageway-forming catheters to facilitate precise positioning and aiming of the catheter, and vi) an apparatus which may be formed within a catheter to prevent a member, apparatus of flow of material from being inadvertently advanced through a lumen of the catheter.

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